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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte MARIA LAURA GENNARO

Appeal 2010-004225
Application 10/009,383
Technology Center 1600

Before TONI R. SCHEINER, DONALD E. ADAMS, and DEMETRA J. MILLS, *Administrative Patent Judges.*

MILLS, *Administrative Patent Judge.*

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

"The invention is based on the inventor's discovery that a polypeptide encoded by an open reading frame (ORF) in the genome of *M. tuberculosis* that is absent from the genome of the Bacille Calmette Guerin (BCG) strain of *M. bovis* elicited a delayed-type hypersensitivity response in animals infected with *M. tuberculosis* but not in animals sensitized with BCG." (Spec. 1.)

The following claims are representative and read as follows:

3. A vector comprising:

(a) a DNA sequence encoding a full length MTBN4 polypeptide, wherein the polypeptide is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis;*

(b) at least one additional DNA sequence encoding a polypeptide which is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis;* and

(c) each DNA sequence being operationally linked to a regulatory sequence allowing expression of the polypeptide encoded by each DNA sequence in a cell.

4. A vector comprising:

(a) a DNA sequence encoding a segment of a full length MTBN4 polypeptide, wherein said segment retains an antigenic property of the polypeptide and wherein the segment is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis;*

(b) at least one additional DNA sequence encoding a segment of a full length polypeptide which is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis;* and

(c) each DNA sequence being operationally linked to a regulatory sequence allowing expression of the segment encoded by each DNA sequence in a cell.

Cited Reference

The Examiner relies on the following prior art reference:

Reed et al.	WO 98/16645	Apr. 23, 1998

Grounds of Rejection

Claims 3-7, 9 and 10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Reed.

Discussion

ISSUE

The Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art to place the sequence [MTBN4] into a vector, transform a host cell with that vector, and to admix said vector with a pharmaceutically acceptable diluent or filler as taught by Reed et al for the other DNA sequences in the document." (Ans. 3.)

Appellant contends that "Reed et al. does not teach or fairly suggest the selection of a DNA sequence encoding MTBN4 for combination with at least one additional DNA sequence encoding a polypeptide that is encoded by *M. tuberculosis* but that is not encoded by the genome of the BCG strain of *M. bovis* to yield the vectors, cells, and compositions of the Pending Claims." (App. Br. 6. (emphasis omitted).)

The issue is: Does Reed teach or suggest combining MTBN4 with at least one additional DNA sequence encoding a polypeptide that is encoded by *M. tuberculosis* but not encoded by the genome of the BCG strain of *M. bovis*?

FINDINGS OF FACT

1. "The claims are drawn to an isolated DNA molecule consisting of a DNA sequence encoding polypeptide MTBN4 or shortened lengths thereof, vectors and cells comprising the DNA." (Ans. 3.)

2. "Instant polypeptide MTBN4 is SEQ ID NO:4. A sequence search for SEQ ID NO:4 indicates that sequence is identical to SEQ ID NO:110 of W098/16645 (Reed). Reed et al not only teach the amino acid sequence of MTBN4, but also teach an isolated DNA comprising the DNA sequence encoding the polypeptide, i.e, a fragment of SEQ. ID. No:109 (Example 3, page 38, lines 22-27). Given that the protein sequence was known, one of ordinary skill in the art would instantly envision a polynucleotide sequence consisting of a DNA encoding said sequence and that said DNA sequence is obvious. Furthermore, it would have been obvious to one of ordinary skill in the art to place the sequence into a vector, transform a host cell with that vector, and to admix said vector with a pharmaceutically acceptable diluent or filler as taught by Reed et al for the other DNA sequences in the document (page 39, line 18 to page 45, line 1; claims 5-8, 40-47)." (*Id.*)

PRINCIPLES OF LAW

"[T]here must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

ANALYSIS

The Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art to place the [MTBN4] sequence into a vector,

transform a host cell with that vector, and to admix said vector with a pharmaceutically acceptable diluent or filler as taught by Reed et al for the other DNA sequences in the document." (*Id.*)

Appellant contends that "Reed et al. does not teach or fairly suggest the selection of a DNA sequence encoding MTBN4 for combination with at least one additional DNA sequence encoding a polypeptide that is encoded by *M. tuberculosis* but that is not encoded by the genome of the BCG strain of *M. bovis* to yield the vectors, cells, and compositions of the pending claims." (App. Br. 6. (emphasis omitted).)

We do not find that the Examiner's has provided evidence to support a prima facie case of obviousness on the record before us. While Reed may disclose that MTBN4 may be combined with other antigens from *M. tuberculosis*, we do not find that the Examiner has provided sufficient evidence that the additional DNA sequence should be one encoding a polypeptide which is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*. Appellants' polypeptides elicited a delayed-type hypersensitivity response in animals infected with M. *tuberculosis* but not in animals sensitized with BCG (Spec. 1), therefore there is a reason that the claims include a negative proviso. Thus Appellants' negative proviso requires that the additional DNA sequence encoding a polypeptide is encoded by *Mycobacterium tuberculosis* but is not encoded by the genome of the Bacille Calmette Guerin (BCG) strain of *Mycobacterium bovis*. The Examiner has not indicated where Reed teaches such a second polypeptide, or provides a reason to select such a polypeptide.

CONCLUSION OF LAW

The Examiner has not provided evidence that Reed teaches or suggests combining MTBN4 with at least one additional DNA sequence encoding a polypeptide that is encoded by *M. tuberculosis* but that is not encoded by the genome of the BCG strain of *M. bovis*.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

REVERSED

alw

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